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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/810,644	03/14/2001	Christen M. Anderson	660088.420D3	7397
500	7590	04/05/2004	EXAMINER	
SEED INTELLECTUAL PROPERTY LAW GROUP PLLC			ANDERSON, REBECCA L	
701 FIFTH AVE				
SUITE 6300			ART UNIT	
SEATTLE, WA 98104-7092			PAPER NUMBER	
			1626	

DATE MAILED: 04/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 09/810,644	Applicant(s) ANDERSON ET AL.	
	Examiner Rebecca L Anderson	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 December 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 85-103 and 107-111 is/are pending in the application.
- 4a) Of the above claim(s) 87,88,90-92,95,97 and 109-111 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 85,86,89,93,94,96,99, 101-103,107 and 108 is/are rejected.
- 7) ☒ Claim(s) 98 and 100 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>3/14/2001</u> . | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

Claims 85-103 and 107-111 are currently pending in the instant application..

Claims 87, 88, 90-92, 95, 97 and 109-111 are withdrawn from consideration as being for a non-elected invention. Claims 98 and 100 are objected. Claims 85, 86, 89, 93, 94, 96, 99, 101-103, 107 and 108 are rejected.

### *Election/Restrictions*

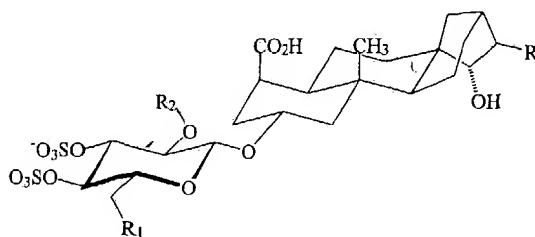
Applicant's election without traverse of Group I, claims 85-103, 107 and 108 along with the election of compound 24 (example 11, page 109) in the paper filed 23 December 2003 is acknowledged.

In response to applicants' statement that:

... In addition , for purpose of initial examination only, Applicants hereby elect the the species of compound 24...

It is noted that as stated on pages 3 and 4 of the previous action, the election of the compound was a further restriction requirement, and according to page 4 of the previous action, upon the election, the Office will review the claims and disclosure to determine the scope of the independent invention encompassing the elected invention based upon class and subclass. The examination will then proceed on the elected invention encompassing the election as defined by common classification. Accordingly, the election of Group I and the further election of the compound 24 has resulted in the following invention, class 536 subclass 119, for search and examination.

**The elected and examined invention is the ANT ligand having the following structure:**



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and stereoisomers and pharmaceutically acceptable salts thereof, wherein:

R1 is -OC(=O)(aryl), -OC(=O)(substituted aryl), -OC(=O)(arylalkyl) or -

OC(=O)(substituted arylalkyl) wherein the substituents on the substituted aryl and substituted arylalkyl are selected from the group consisting of halogen, hydroxy, alkyl, haloalkyl, aryl and arylalkyl;

R2 is hydrogen or -C(=O)R5;

R3 is CH<sub>3</sub> or =CH<sub>2</sub> and

R5 is alkyl.

The remaining subject matter of claims 85, 86, 89, 93, 94, 96, 98-103, 107 and 108 that is not drawn to the above elected invention and the subject matter of claims 87, 88, 90-92, 95, 97 and 109-111 stands withdrawn under 37 CFR 1.142(b) as being for non-elected subject matter. The remaining products which are not within the elected invention, which are independent and distinct from the elected invention and do not have unity with the elected products and therefore are withdrawn by means of a restriction requirement within the claims are, for example, the products of the above formula wherein R1 is hydroxyl, halogen or NHR<sub>4</sub> and wherein X is an amido or alkylamido linker and wherein R<sub>4</sub> contains a heteroaryl or heteroarylalkyl, etc.

The above mentioned withdrawn products which are withdrawn from consideration as being for nonelected subject matter differ materially in structure and composition. The withdrawn products which differ from those of the elected invention, which comprises a carboxyatractyloxide (536/119), are, for example, products containing a nitrogen containing group, such as pyrrolidino groups, piperidino or

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morpholino, etc. or products containing a halogen which are chemically recognized to differ in structure and function. This recognized chemical diversity of the functional groups can be seen by the various classification of these functional groups in the U.S. classification system, i.e. class 536 subclasses 18.7(+) (nitrogen containing), class 536 subclasses 122(+) (halogen containing), etc. Therefore, again, the products which are withdrawn from consideration as being for non-elected subject matter differ from the elected invention and have been restricted properly as a reference which anticipated but the elected subject matter would not even render obvious the non-elected subject matter.

These withdrawn products are independent and distinct from the elected invention and do not have unity with the species elected and are therefore withdrawn by means of a restriction requirement within the claims.

### ***Claim Objections***

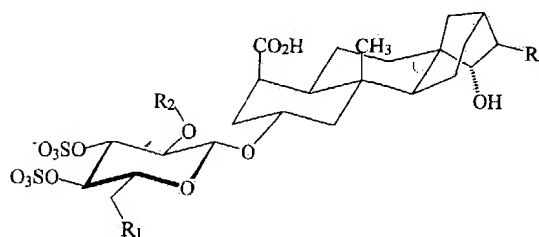
Claims 85, 86, 89, 93, 94, 96, 98-103, 107 and 108 are objected to as containing non-elected subject matter. Claims 98 and 100 is also objected to as being dependent upon a rejected base, but would appear to be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims and limited to the elected invention identified supra.

### ***Claim Rejections - 35 USC § 102***

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 85, 86, 89, 93, 94, 96, 99, 101-103, 107 and 108 are rejected under 35 U.S.C. 102(b) as being anticipated by Boulay et al., Analytical Biochemistry 128, 323-330 (1983).

Applicants instant elected invention is:  
the ANT ligand having the following structure:



and stereoisomers and pharmaceutically acceptable salts thereof, wherein:

R1 is -OC(=O)(aryl), -OC(=O)(substituted aryl), -OC(=O)(arylalkyl) or -OC(=O)(substituted arylalkyl) wherein the substituents on the substituted aryl and substituted arylalkyl are selected from the group consisting of halogen, hydroxy, alkyl, haloalkyl, aryl and arylalkyl;  
R2 is hydrogen or -C(=O)R5;  
R3 is CH3 or =CH2 and  
R5 is alkyl.

Boulay et al. discloses the compound of 6'-O-naphthoyl ATR in figure 1, page 324 which corresponds to applicants instant invention wherein R1 is -OC(=O)naphthyl, R2 is -C(=O)R5, R3 is =CH2 and R5 is -CH2-CH(CH3)2. Boulay et al. discloses pharmaceutical compositions on page 328, Figure 6.

Claims 85, 86, 89, 93, 94, 96, 99, and 101-103 are rejected under 35 U.S.C. 102(b) as being anticipated by Block et al., Methods in Enzymology, 125, 639—649 (1986).

Block et al. discloses the compound of 6'-O-naphthoyl ATR in figure 3, page 645 which corresponds to applicants instant invention wherein R1 is  $-\text{OC}(=\text{O})\text{naphthyl}$ , R2 is  $-\text{C}(=\text{O})\text{R5}$ , R3 is  $=\text{CH}_2$  and R5 is  $-\text{CH}_2-\text{CH}(\text{CH}_3)_2$ .

Claims 85, 86, 89, 93, 94, 96, 99, 101-103, 107 and 108 are rejected under 35 U.S.C. 102(b) as being anticipated by Roux et al., Analytical Biochemistry 234, 31-37 (1996).

Roux et al. discloses the compound of 6'-O-naphthoyl ATR in figure 1, page 32 which corresponds to applicants instant invention wherein R1 is  $-\text{OC}(=\text{O})\text{naphthyl}$ , R2 is  $-\text{C}(=\text{O})\text{R5}$ , R3 is  $=\text{CH}_2$  and R5 is  $-\text{CH}_2-\text{CH}(\text{CH}_3)_2$ . Roux et al. discloses pharmaceutical compositions on page 34, Figure 2 wherein N-ATR is mixed with KCl.

### **Conclusion**

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rebecca L. Anderson whose telephone number is (571) 272-0696. Mrs. Anderson can normally be reached Monday through Friday 5:30AM to 2:00PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Joseph McKane, can be reached at (571) 272-0699.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone numbers are (703) 308-1235 and (703) 308-0196.

A facsimile center has been established. The hours of operation are Monday through Friday, 8:45AM to 4:45PM. The telecopier number for accessing the facsimile machine is (703) 872-9306



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Rebecca Anderson  
Patent Examiner  
Art Unit 1626, Group 1620  
Technology Center 1600

for



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Joseph McKane  
Supervisory Patent Examiner  
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